

REMARKS

Reconsideration of the allowability of the present application is respectfully requested.

Status of the Claims

Prior to the issuance of the Office Action, applicants had canceled all pending claims other than claims 96 and 97 which had been allowed in an earlier Office Action. Applicants also sought to reintroduce the canceled subject matter by the addition of new claims (identified in the Reply as claims 110-158) which depended from the allowed claims, but these new claims were not entered. As a result, only claims 96 and 97 were acted upon by the Examiner in the Office Action. Also, insofar as claims 110-158 were not entered, the new claims presented herein begin with 110 which is still the next number following the highest previously numbered claim.

Support for new claims 110-177 presented herein is found throughout the specification and specifically in the canceled claims on which they are (entirely or in large part) modeled. In order to assist the Examiner in readily confirming the close correspondence of the new claims with canceled claims, applicants present the following table detailing this correspondence for each new claim for which such correspondence may be found.

<u>Canceled Claim</u>	<u>New Claim</u>
1	110
3	111
4	112
5	113
6	114
7	115
8	116
9	117
10	118
1	120
11	121
22, 25, 31	122
11	123
21	124
13	125
14	126

15	127
16	128
21	129
11	130
27	131
28	132
29	133
30	134
32	135
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34	137
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36	139
47	142
53	144
54	145
55	146
56	147
57	148
58	149
59	150
60	151
61	152
53	153
62	154
22, 25, 31	155
11	156
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14	159
15	160
16	161
21	162
11	163
27	164
28	165
29	166
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36	172
65	173
66	174
41	175
39	176
63	177

Remarks Concerning Rejections in Office Action

In view of the applicants' cancellation of claims 96 and 97 as set forth in the above Listing of Claims, applicants respectfully request that the rejections set forth in the Office Action be withdrawn as moot. Notwithstanding the mootness of the rejection of now-canceled claims, applicants provide the following comments to assist the Examiner in understanding the cited reference and its differences from the claimed invention.

According to the Examiner, Bachynsky teaches a process for providing a blend of a macromolecular drug (ceftriaxone) and a salt of a medium chain fatty acid having a carbon chain length of from 6 to 20 carbon atoms, with optional constituents Laureth 12 and Witepsol[®] H15. The Examiner further characterizes the blend of Bachynsky, as well as each constituent thereof, as solids at room temperature, and that the blend of Bachynsky as capable of forming an oral dosage form in which the sodium caprylate serves as an enhancer. Applicants respectfully submit that the Examiner's characterization of Bachynsky, however, is factually erroneous and, as a result, the rejections of record are without basis.

As an initial matter, it is noted that the active compound disclosed in Bachynsky which the Examiner asserts to be a macromolecule (i.e., ceftriaxone) is not actually macromolecular. The chemical formula of ceftriaxone sodium is $C_{18}H_{16}N_8Na_2O_7S_3 \cdot 3.5 H_2O$ and has a calculated molecular weight of 661.59. By contrast, "macromolecular" is a term generally used to refer to compounds having a molecular weight in excess of 1,000. *See, e.g.,* Hackh's Chemical Dictionary at 400 (defining "macromolecular chemistry" as "the study of the preparation, properties, and uses of substances containing large and complex molecules, i.e., mol. wt. exceeding 1,000."), a copy of which is attached as Exhibit "A."

More importantly, the Examiner's characterization of Laureth 12 as a solid is factually incorrect. According to its Material Safety Data Sheet (MSDS), and contrary to the Examiner's characterization, Laureth 12 has the appearance of a "pale yellow liquid." *See* MSDS at Section 9, a copy of which is attached as Exhibit "B." Stated simply, Bachynsky does *not* disclose compositions in which each constituent is a solid at room temperature. Rather, Bachynsky's teachings are limited to compositions which comprise at least one liquid component (i.e., Laureth 12).

In view of this clear limitation to the scope of its disclosure, Bachynsky does not anticipate nor render obvious the pending claims insofar as they require that the

“blend and each of said drug, enhancer, and optional constituent(s) is a solid at room temperature.” Moreover, claims reciting that the medium chain fatty acid salt (or derivative) is the only enhancer present in the composition are similarly neither taught nor suggested by Bachynsky. Accordingly, Bachynsky cannot serve as the basis for a rejection of the pending claims.

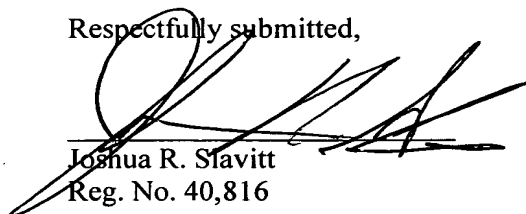
Remarks Concerning the Listing of Claims

Applicants respectfully submit that the Listing of Claims set forth above places this case in condition for allowance. All of the claims for which rejections had been maintained in the Office Action have been canceled, and new claims 110-177 presented herein are patentable over the publications of record for the reasons set forth herein and in prior submissions of the applicants.

Conclusion

In view of the foregoing amendments and remarks, applicants respectfully request favorable consideration and early issuance of a Notice of Allowance. If any issues remain, the undersigned requests a telephone interview prior to the issuance of an action.

Respectfully submitted,



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M

M. (1) Symbol for metal. (2) Abbreviation for mega, or million. **M acid.** 1-Amino-5-naphthol-4-sulfonic acid.

M. Symbol for: (1) mass, (2) molal, (3) molecular weight, (4) the mathematical constant $\log_e 10 = 0.43429, 44819$. M^{-1} The mathematical constant $\log_e 10 = 2.30258, 50930$. **M electron.** The electron of the *M* shell or *M* orbit, q.v. **M orbit.** The third layer or energy level, in which electrons move around the proton in the dynamic atom. **M. radiation.** A series of homogeneous X rays characteristic of the metal used as anticathode, and fainter than the *K* and *L* series. **M series.** The spectral lines produced by the *M* radiations on diffraction through a crystal grating. Cf. *Moseley spectra*. **M shell.** The third layer or energy level, in which electrons oscillate in the static atom.

m. Abbreviation for: (1) meter, (2) milli-, or one-thousandth part. **m².** Abbreviation for square meter. **m³.** Abbreviation for cubic meter. Cf. *mm*, *mmm*.

m. Symbol for: (1) meta position, (2) metastable state.

ℳ. Abbreviation for minim.

μ. Greek mu. (1) Abbreviation for: (a) icron, (b) micro-, or one-millionth of a unit. (2) Symbol for: (a) meso position, (b) magnetic permeability. Cf. *mμ*, *μμ*.

Ma. Symbol for masurium.

ma. Abbreviation for milliampere.

Mac. See also *Mc*.

macassar oil. Yellow fat from the seeds of *Schleichera trijuga*, India and Malaysia.

mace. Macis. The dried covering tissues of the seeds of *Myristica fragrans*; a condiment. **m. oil.** An essential oil from mace. Colorless liquid, d.0.91; a flavoring.

macene. $C_{10}H_{18} = 138.1$. A terpene from mace oil.

maceral. General name for the microscopic structures of the mineral constituents of coals.

macerate. To break up a solid by soaking in a liquid.

Mache, Heinrich. Austrian physicist. born, 1876.

m. unit. M.E. The quantity of radioactive emanation which produces a saturation current of one-thousandth of an electrostatic unit. 1 curie = 2.8×10^9 maches. 1 mache = 3.64×10^{-10} curie/liter = 3.64 eman.

machine steel. A steel containing less than 0.3% carbon; easily machined.

macht metal. A forging alloy containing Cu 60, Zn 38, Fe 2%.

Mach unit. A unit of velocity, expressed as a percentage of the velocity of sound at sea level.

mackay bean. The dried seeds of *Entada scandens* (Leguminosae), Queensland; a coffee substitute.

mackenite metals. A group of heat-resisting Ni-Cr or Ni-Cr-Fe alloys.

Mackenzie amalgam. An amalgam made by grinding

together the solid alloys Hg-Bi and Pb-Hg.

Mackey test. A test of the autoxidation fire hazards of oils.

maclayine. $C_{17}H_{35}O_{11} = 412.26$. An alkaloid from *Illipe maclayana* (Sapotaceae), the tropics.

macle. (1) A variety of andalusite. (2) A twin crystal.

MacLeod, John James Rickard. 1876-1935. Scottish-Canadian biochemist, awarded Nobel Prize (with Banting) in 1923 for share in discovery of insulin.

macleyine. Protopine.

maclurin. $C_6H_3(OH)_2CO.C_6H_2(OH)_2 = 280.1$. Pentahydroxybenzophenone, osage orange (q.v.), moringatannic acid. Yellow crystals from the wood of *Maclura aurantiaca*, m.200, soluble in hot water; a dye.

macro- Prefix (Greek μακρός = broad), indicating "large."

macroaxis. The long axis in orthorhombic or triclinic crystals.

macrobacterium. A large bacterium.

macrocarpine. An alkaloid from *Thalictrum macrocarpum* (Ranunculaceae). Yellow crystals, soluble in water.

macrochemistry. (1) The chemistry of reactions that are visible to the unaided eye. Cf. *microchemistry*. (2) Chemical operations on a large scale.

macrocylic. Containing rings of more than 7 C atoms.

macrodome. See *dome*.

macrofarad. Megafarad.

macrograph. Photomacrograph.

macrolide. A substance having a macrocyclic lactone structure; as, streptomycin.

macromolecular chemistry. The study of the preparation, properties, and uses of substances containing large and complex molecules: i.e., mol. wt. exceeding 1,000. Cf. *polymer*.

macroscopic. Describing objects visible to the naked eye. Cf. *microscopic*.

macrotin. Cumicifugin.

macrotoad. The combined principles from the root of *Cimicifuga racemosa*; an antispasmodic.

macrotyls. Cimicifuga.

maculanin. Potassium amylate.

madder. Turkey red, q.v. Garance. The root of *Rubia tinctorum* species. It contains glucosides which yield, on fermentation, alizarin and purpurin; a dye and pigment in lakes.

Maddrell salt. A long-chain, high-molecular-weight sodium metaphosphate, made by heating sodium metaphosphate at 300; soluble in potassium salt solutions.

mafic. A rock-forming material, mainly magnesium and iron silicates.

mafurite. A mineral association of kieserite and augite, q.v.



MATERIAL SAFETY DATA SHEET

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1. PRODUCT IDENTIFICATION

Product Name: **LUMULSE™ L-12**
CTFA NAME: **Laureth-12**

2. COMPOSITION / INFORMATION ON INGREDIENTS

	CAS Number	Weight %	ACGIH TLV	OSHA PEL
Lauryl alcohol, ethoxylated	9002-92-0		Not est.	Not est.

3. HAZARDS IDENTIFICATION

Potential Health Effects

INHALATION: Negligible unless heated to produce vapors. Vapors or finely misted materials may irritate the mucous membranes and cause irritation, dizziness, and nausea. Remove to fresh air.

EYE CONTACT: May cause irritation. Irrigate eye with water for at least 15 to 20 minutes. Seek medical attention if symptoms persist.

SKIN CONTACT: Prolonged or repeated contact is not likely to cause significant skin irritation. Material is sometimes encountered at elevated temperatures. Thermal burns are possible.

INGESTION: No hazards anticipated from ingestion incidental to industrial exposure.

4. FIRST AID MEASURES

EYES: Irrigate eyes with a heavy stream of water for at least 15 to 20 minutes.

SKIN: Wash exposed areas of the body with soap and water.

INHALATION: Remove from area of exposure, seek medical attention if symptoms persist.

INGESTION: Give one or two glasses of water to drink. If gastro-intestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person.)

5. FIRE FIGHTING MEASURES

FLASH POINT (Method Used): > 175°C (COC)

FLAMMABILITY LIMITS: None known

EXTINGUISHING MEDIA: Dry chemical, foam, halon, CO₂, water spray (fog). Water stream may splash burning liquid and spread fire.

SPECIAL FIRE FIGHTING PROCEDURES: Use water spray to cool drums exposed to fire.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Firefighters should use self-contained breathing apparatus

to avoid exposure to smoke and vapor.

6. ACCIDENTAL RELEASE MEASURES

SPILL CLEAN-UP PROCEDURES: Remove sources of ignition, contain spill to smallest area possible. Stop leak if possible. Pick up small spills with absorbent materials such as paper towels, "Oil Dry", sand or dirt. Recover large spills for salvage or disposal. Wash hard surfaces with safety solvent or detergent to remove remaining oil film. Greasy nature will result in a slippery surface.

7. HANDLING AND STORAGE

Store in closed containers between 50°F and 120°F. Keep away from oxidizing agents, excessive heat, and ignition sources. Store and use in well ventilated areas. Do not store or use near heat, spark, or flame; store out of sun. Do not puncture, drag, or slide this container. Drum is not a pressure vessel; never use pressure to empty.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION: If vapors or mists are generated, wear a NIOSH approved organic vapor/mist respirator.

PROTECTIVE CLOTHING: Safety glasses, goggles, or face shield recommended to protect eyes from mists or splashing. PVC coated gloves recommended to prevent skin contact.

OTHER PROTECTIVE MEASURES: Employees must practice good personal hygiene, washing exposed areas of skin several times daily and laundering contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point, 760mm Hg:	> 200°C
Specific Gravity, (H ₂ O=1):	0.94
Vapor Pressure, mm Hg:	< 1
Vapor Density, (Air=1):	> 1
Volatiles, % by Volume:	< 1%
Evaporation Rate, (Butyl Acetate=1):	< 1
Solubility in Water, % by Volume:	Dispersible
Appearance and Odor:	Pale yellow liquid with a bland odor

10. STABILITY AND REACTIVITY

GENERAL: This product is stable and hazardous polymerization will not occur.

INCOMPATIBLE MATERIALS AND CONDITIONS TO AVOID: Strong oxidizing agents

HAZARDOUS DECOMPOSITION PRODUCTS: Combustion produces carbon monoxide, carbon dioxide along with thick smoke.

11. DISPOSAL CONSIDERATIONS

Waste may be disposed of by a licensed waste disposal company. Contaminated absorbent material may be disposed of in an approved land fill. Follow local, state and federal disposal regulations.

12. TRANSPORT INFORMATIONUN HAZARD CLASS: N/A

13. REGULATORY INFORMATION

OSHA STATUS: This product is not hazardous under the criteria of the Federal OSHA hazard Communication Standard 29 CFR 1910.1200. However, thermal processing and decomposition fumes from this product may be hazardous as noted in Section 3.

TSCA STATUS: The components of this product are listed on TSCA.

14. OTHER INFORMATION:

NFPA Codes: Health: 1 Fire: 1 Reactivity: 0

Revision Notes:

3/9/04 Creation of MSDS

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. Such information is to the best of the company's knowledge and believed accurate and reliable as of the date indicated. However, no representation, warranty or guarantee of any kind, express or implied, is made as to its accuracy, reliability or completeness and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of use. It is the user's responsibility to satisfy himself as to the suitability and completeness of such information for his own particular use.